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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,084	08/20/2003	Yoshimi Takai	2144.0100000/RWE/ALS	4948

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STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
BASI, NIRMAL SINGH	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,084	TAKAI ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *2,7-13 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6 and 14-19* is/are rejected.

7)☒ Claim(s) *1 and 16-18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 August 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Sequence listings

DETAILED ACTION

1. Amendment filed 8/2/06 has been entered.

2. IDS filed 6/9/03 has been entered and considered. IDS filed 10/6/05 has been entered and considered.

Election/Restriction

3. Applicant's election without traverse of Group I (claims 1, 3-6, 14-18), pertaining to SEQ ID NOs:1 and 2 on 6/2/06 is acknowledged. Claims 2, 7-13 and 19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The requirement is still deemed proper and is therefore made FINAL.

Objections

4. The drawings are objected to because Figure 2 is too dark and the writing is not legible.

Appropriate correction is required.

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application for the reasons given above. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Objection to claims:

5. Claims 1 and 16-18 must be amended to remove non-elected subject matter (pertaining to SEQ ID NOs:3 and 4).

6. Claim 4 objected to because it contains an improper Markush group. The "host cell" and "vector" do not share substantial structural features to be included in the same Markush group.

Sequence Rules Compliance

7. This application fails to comply with the sequence rules, 37 CFR 1.821-1.825. Nucleotide and peptide sequences must be identified with the corresponding SEQ ID NO. Title 37, Code of Federal Regulations, Section 1.821 states "reference must be made to the sequence by use of the assigned identifier", the identifier being SEQ ID NO. Figure 2A contains sequences but corresponding SEQ ID NOs. Compliance with sequence rules is required.

Right of Priority

8. Applicant has claimed foreign priority to "JAPAN 2002-284263" but has not provided a translation of the foreign priority document.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Examiner requires an English translation foreign priority document for the purpose of determining the applicant's right to rely on the foreign filing date.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

9. Claims 1, 4, 6 and 14-18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1, 4, 6 and 14-18 recite polynucleotides but do not recite that they are isolated or purified. The claims as currently recited encompass naturally occurring compounds. Therefore, the compounds as claimed are a product that occurs in nature and does not show the hand of man, and as such is non-statutory subject matter. It is suggested that the claims be amended to recite "an isolated and purified" to overcome this rejection.

Claims 4 recites "host cell carrying the polynucleotide of claim 1" but do not recite that it is isolated or purified. The claims as currently recited encompass naturally occurring compounds. Therefore, the compounds as claimed are a product that occurs in nature and does not show the hand of man, and as such is non-statutory subject matter. It is suggested that the claims be amended to recite "an isolated and purified" to overcome this rejection.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 3-6, 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (d) and 6 are indefinite because "stringent conditions" for hybridization are not specified. The metes and bounds of the group of sequences that would meet the limitations of the claim depend upon the precise conditions under which hybridizations were performed including wash conditions. Since the hybridization and wash conditions dictate which nucleic acid sequences remain specifically bound to nucleic acid shown in SEQ ID NO:1 the metes and bounds of the claims cannot be determined without the disclosure of said conditions.

Claim 1 (c) is indefinite because the use of the language stating, "in which the amino acids are substituted, deleted, inserted and/or added". For example, if all the amino acids are deleted there is nothing left. In essence by using a combination of "substituted, deleted, inserted and/or added" applicant has removed all structural limitations on the polypeptide.

Claim 1(b) is indefinite because it is not clear if applicant is claiming a polynucleotide comprising any coding region of the nucleotide sequence of SEQ ID NO:1, in which case it can comprise a polypeptide that contains as little as three nucleotides, or claiming a polynucleotide comprising the complete coding region which encodes the polypeptide of SEQ ID NO:2. The claim uses the language, "polynucleotide comprising **a coding region**" and because of "a" instead of "the" Examiner has interpreted the claim to mean the claim

encompasses a polynucleotide containing any coding region, which encompasses every protein known to man. Further it is not clear what the "coding region" refers to. Does it refer to the region of the polynucleotide of SEQ ID NO:1 that encodes the polypeptide of SEQ ID NO:2 or something else.

Claim 4 is indefinite because it is not clear what is meant by host cell "carrying" the use polynucleotide of claim 1. How is the polynucleotide carried? It applicant is claiming host cell comprising the polynucleotide of claim then the claim should be amended accordingly to overcome the rejection.

Claims 3, 5 and 14-18 are rejected for depending on an indefinite base claim and fail to resolve the issued raised above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11 Claim 1, 3-6, 14-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a polypeptide which binds afadin, α–actinin-1 or α–actinin-2, wherein the polypeptide comprises the afadin, actininα or actininβ binding domain disclosed in Figure 3A, vector comprising said polynucleotide, isolated host cell comprising said vector, method of using said cell to produce the enabled

polypeptide of claim 1; and polynucleotide fragments of the polynucleotide of SEQ ID NO:1 which are of sufficient length to be used as specific hybridization probes to detect the polynucleotide encoding the polypeptide which binds afadin, actininα or actininβ, wherein the polypeptide comprises the afadin, α–actinin-1 or α–actinin-2 binding domain disclosed in Figure 3C, does not reasonably provide enablement for other polynucleotides. The, specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Based on the disclosure a person of ordinary skill in the art would, in light of the specification, be able to isolate polynucleotide encoding a polypeptide which binds afadin, α–actinin-1 or α–actinin-2, comprising the afadin, α–actinin-1 or α–actinin-2 binding domain disclosed in Figure 3C. A person of ordinary skill in the art , in light of the specification, would also be able to produce vector comprising the enabled polynucleotide and host cell comprising said vector and use said host cell to produce the enabled polynucleotide of claim 1.

The scope of the claims, which encompass other polynucleotides encoding polypeptides not comprising the afadin, actininα or actininβ binding domain disclosed in Figure 3C are not enabled by the disclosure. Further the scope of the claims, which encompass other polynucleotides encoding polypeptides comprising the afadin or actinin binding activity but structurally unrelated to the polynucleotide of SEQ ID NO:1 are not enabled by the disclosure. The specification, Figure 3A, discloses the critical structural regions

of the polypeptide of SEQ ID NO:2 (ADIP) which is required for afadin, α–actinin-1 or α–actinin-2 binding. ADIP has been shown to bind afadin, α–actinin-1 or α–actinin-2. The claims encompass variant polynucleotides which may have as little a 6 nucleotides in common with the polynucleotide of SEQ ID NO:6 and none of the afadin, α–actinin-1 or α–actinin-2 binding. Applicant has not disclosed how to use said variants. The claims also encompass unspecified "stringent conditions" for hybridization. The undisclosed "stringent conditions" for hybridization do not provide a meaningful structural limitation by which to isolate the polynucleotides which encode the polypeptides with afadin, α–actinin-1 or α–actinin-2 binding activity. Variant molecules which are structurally unrelated to ADIP are encompassed by the claims. Although these molecules may bind afadin, actinin they may have physiological functions unrelated to the ADIP of instant invention. Applicant has not disclosed how to use said variant molecules. The scope of the group of polynucleotide that would meet the limitations of the claimed invention depend upon the precise conditions under which hybridizations were performed including wash conditions. Since the hybridization and wash conditions dictate which nucleic acid sequences remain specifically bound to nucleic acid shown in SEQ ID NO:1 the scope the claims encompasses unrelated molecules, both naturally and un-naturally occurring. For example, Applicant has not shown how to use variant polynucleotides comprising 15 nucleotides that hybridize to the polynucleotide of SEQ ID NO:1. Said variant polynucleotides comprising 15 nucleotides may be not even contain the critical feature of the invention as it relates structure to function.

Pertaining to claims with hybridization language the instant fact pattern closely resembles that in Ex parte Maizel, 27 USPQ2d 1662 (BPAI 1992). In Ex parte Maizel, the claimed invention was directed to compounds which were defined in terms of function rather than sequence (i.e., "biologically functional equivalents"). The only disclosed compound in both the instant case and in Ex parte Maizel was the full length, naturally occurring protein. The Board found that there was no reasonable correlation between the scope of exclusive right desired by Appellant and the scope of enablement set forth in the patent application. Even though Appellant in Ex parte Maizel urged that the biologically functional equivalents would consist of proteins having amino acid substitutions wherein the substituted amino acids have similar hydrophobicity and charge characteristics such that the substitutions are "conservative" and do not modify the basic functional equivalents of the protein, the Board found that the specification did not support such a definition, and that the claims encompassed an unduly broad number of compounds. Such is the instant situation. The hybridization conditions do not provide a meaningful structural limitation. Clearly, a single disclosed sequence does not support claims to any nucleic acid hybridizing to same, given the lack of guidance regarding what sequences would hybridize specifically to SEQ ID NO: 1, and not other, related sequences.

Due to the large quantity of experimentation necessary to make or identify the variant polynucleotides of claimed invention lacking with no disclosed critical feature of the invention as it relates structure to function, the lack of direction/guidance presented in the specification regarding the identification,

purification, isolation and characterization of said variant polynucleotides, the unpredictability of the effects of mutation on the structure and function of variant polynucleotides (since mutations of SEQ ID NO:1 and 2 are also encompassed by the claim), and the breadth of the claim which fail to recite meaningful structural and functional limitations, undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope.

12. Claims 1, 3-6 15, 16-18 are rejected under 35 U.S.C. 1 12, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant ad that the inventors), at the time the application was filed, had possession of the claimed invention. The claims are drawn to:

Claim 1 (b) and 15 A polynucleotide comprising **a** coding region of the nucleotide sequence of SEQ ID NO: 1.

This claim encompasses any polynucleotide, which can be as little as any one coding region SEQ ID NO: 1, i.e. three consecutive nucleotides.

Claim 1, (c), 16, 17 A polynucleotide comprising a nucleotide sequence encoding a protein having binding activity to afadin or actinin and comprising the amino acid sequence of SEQ ID NO: 2 or 4, in which the amino acids are substituted, deleted, inserted and/or added.

This claim has no structural limitation only functional limitations; by using a

combination of "substituted, deleted, inserted and/or added" applicant has removed all structural limitations on the polypeptide.

Claim 1 (d) A polynucleotide which hybridizes under stringent conditions with a DNA comprising the nucleotide sequence of SEQ ID NO:1 and which encodes protein having binding activity to afadin or actinin.

In this case "stringent conditions" for hybridization are not specified. The scope of the group of sequences that would meet the limitations of the claim depend upon the precise conditions under which hybridizations were performed including wash conditions. Since the hybridization and wash conditions dictate which nucleic acid sequences remain specifically bound to nucleic acid shown in SEQ ID NO:1 the scope bounds of the claims cannot be determined. In essence the claim as written has no clear structural limitation.

Claim 3 A vector into which the polynucleotide of claim 1 is inserted.

Claim 4 A host cell carrying the polynucleotide of claim 1 or a vector into which the polynucleotide of claim 1 is inserted.

Claim 5 A method for producing the polypeptide encoded by the polynucleotide of claim 1

Claim 6 A polynucleotide which specifically hybridizes under highly stringent conditions to the polynucleotide of claim 1 and which comprises at least 15 nucleotides.

Again "stringent conditions" for hybridization are not specified. The scope of the group of sequences that would meet the limitations of the claim depend upon the precise conditions under which hybridizations were performed including wash conditions. Since the hybridization and wash conditions dictate which nucleic acid sequences remain specifically bound to nucleic acid shown in SEQ ID NO:1 the scope bounds of the claims cannot be determined. In essence the claim as written only requires that the polynucleotide comprise at least 15 nucleotides.

The specification discloses a polynucleotide (SEQ ID NO:1) encoding a polypeptide (SEQ ID NO:2) which binds afadin, α–actinin-1 or α–actinin-2, wherein the polypeptide comprises the afadin, actininα or actininβ binding domain disclosed in Figure 3A. The specification also discloses truncated polynucleotide of SEQ ID NO:1 encoding truncated polypeptide SEQ ID NO:2 which binds afadin, α–actinin-1 or α–actinin-2, wherein the polynucleotide comprises the afadin, actininα or actininβ binding domain disclosed in Figure 3A. The specification is enabled for polynucleotide encoding polypeptide which bind afadin, α–actinin-1 or α–actinin-2, wherein the polypeptide comprises the afadin, actininα or actininβ binding domain disclosed in Figure 3A.

The critical feature of the invention as it relates structure to function is the afadin, actininα or actininβ binding domain disclosed in Figure 3A. The structure is the domain contained in the polypeptide of SEQ ID NO:1, and the function is that said domain binds afadin, actininα or actininβ. The structure has to be a minimum length and composition. The critical feature of the invention as it

relates to structure and function is not contained, for example, in a polynucleotide that is 15 nucleotides long as claimed in claim 6.

The claims, as written, encompass polynucleotides, which vary substantially in length and also in nucleotide composition. The instant disclosure does not adequately describe the scope of the claimed genus which has insufficient structural limitations to correspond to the functional limitations. The claims encompass a substantial variety of subgenera including derivatives, allelic variants, chimeric constructs, fusion constructs etc. which may not even contain the critical structural feature of the invention contained in the afadin, actininα or actininβ binding domain of ADIP.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. As cited above many polynucleotide constructs which combine specific structure to function are enabled by the disclosure, the claims that do not, as indicted above, are not enabled.

Pertaining to the claims that are not enabled by the disclosure there is no identification of any particular portion of the structure of the peptide of SEQ ID NO:2 that must be conserved for activity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. The

structural limitations in the claim are insufficient to define the genus claimed, which encompasses unrelated peptides.

Naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. When one is unable to envision the detailed constitution of a complex chemical compound having a particular function, such as a peptide or nucleic acid, so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the peptide or nucleic acid has been isolated. Thus, claiming all peptides or DNAs that achieve a result without defining what means will do so is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. The claims recite a broad arbitrary structural relationship between the claimed polynucleotide sequence and the disclosed polynucleotide of SEQ ID NO:1. Therefore, unrelated peptides to SEQ ID NO:2 are encompassed by the claims.

While one of skill in the art can readily envision numerable species of amino acid sequences that are at least a given % identity to a reference peptide sequence, one cannot envision which of these also encode a peptide with a specific activity of the peptide of SEQ ID NO:2 without encompassing the structural domains which bind afadin, actininα or actininβ as disclosed in Figure 3. The fact remains that the actual peptide, with a particular activity, or the actual amino acid sequences of such a peptide *cannot* be envisioned any better when the possible choices are narrowed from all possible sequences to all possible

sequences with an arbitrary structural relationship. For example, if one skilled in the art were to make a synthetic polynucleotide which hybridized to the polynucleotide of SEQ ID NO:1 and consisted of 16 nucleotides he/she would not be able to say whether it was a functional peptide belonging to the claimed genus than a polynucleotide that consisted of 76 nucleotides. Nor would he be able to say whether the sequence existed in nature.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 , clearly states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description" inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the ad to recognize that (he or she) invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of peptide, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird,* 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF'S were found to be unpatentable due to lack of written description for that broad class.

The specification provided only the bovine sequence.

Therefore, only isolated peptide comprising the amino acid sequence set forth in SEQ ID NO:2 but not the full breadth of the claims meets the written description provision of 35 U.S.C.112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1 115).

Therefore the specification is enabled for polynucleotide encoding polypeptide which bind afadin, α–actinin-1 or α–actinin-2, wherein the polypeptide comprises the afadin, actininα or actininβ binding domain disclosed in Figure 3A.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1,3, 4, 6, 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by The RIKEN Genome Exploration Research group Phase II Team and the FANTOM Consortium (Nature, Vol. 409, pages 563-690, February 8, 2001)

The RIKEN Genome Exploration Research group Phase II Team and the FANTOM Consortium (Nature article, also see attached sequence comparison) disclose a polynucleotide, which has 99.4% query match and 99.9% identity to the polynucleotide of SEQ ID NO:1. Also disclosed are vector comprising said polynucleotide and cell comprising said vector. Therefore the disclosure of the RIKEN Genome Exploration Research group Phase II Team and the FANTOM Consortium meets the limitations of claims 1,3, 4, 6, 15-18, absent evidence to the contrary.

14. Claims 1,3, 4, 6, 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Carninci et. al. (Genome Resaerch, Vol. 10, pages 1617-1630, 2000)

Carninci et. al. (also see attached sequence comparison) disclose a polynucleotide, which has 99.4% query match and 99.9% identity to the polynucleotide of SEQ ID NO:1. Also disclosed are vector comprising said polynucleotide and cell comprising said vector. Therefore the disclosure of Carninci et. al. meets the limitations of claims 1,3, 4, 6, 15-18, absent evidence to the contrary.

15. Claims 1,3, 4, 6, 15-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Takao Isogai et al (US Patent 6,943,241)

Takao Isogai et al (also see attached sequence comparison) disclose a polynucleotide, which has 46.8% query match and 77.2% identity to the polynucleotide of SEQ ID NO:1. Takao Isogai et al also disclose a polypeptide, which has 68.0% query match and 90.3% identity to the polypeptide of SEQ ID NO:2. Further disclosed is vector comprising said polynucleotide and cell comprising said vector. Method of producing polypeptide using said cell is also disclosed. Therefore the disclosure of the Takao Isogai et al meets the limitations of claims 1,3, 4, 5, 6, 15-18, absent evidence to the contrary.

16. Claims 1,3, 4, 5, 6, 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Helix Res Inst (EP1074617 see ids)

Helix Res Inst (also see attached sequence comparison) disclose a polynucleotide, which has 46.8% query match and 79.7% identity to the polynucleotide of SEQ ID NO:1. Helix Res Inst also disclose a polypeptide, which has 58.6% query match and 85.6% identity to the polypeptide of SEQ ID NO:2. Further disclosed is vector comprising said polynucleotide and cell comprising said vector. Method of producing polypeptide using said cell is also disclosed. Therefore the disclosure of the Helix Res Inst et al meets the limitations of claims 1,3, 4, 5, 6, 15-18, absent evidence to the contrary.

17. Claims 1,3, 4, 6, 14-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Mammalian Gene Collection (MGC) Program team (PNAS, Vol. 99, pages 16899-16903), December 24, 2002)

MGC Program team (also see attached sequence comparison) disclose a polynucleotide, which has 99.9% query match and 99.9% identity to the polynucleotide of SEQ ID NO:1. MGC Program team also disclose the polynucleotide encodes a polypeptide that has 100% query match and 100% identity to the polypeptide of SEQ ID NO:2. Further disclosed is vector comprising said polynucleotide and cell comprising said vector. Therefore the disclosure of the MGC Program meets the limitations of claims 1,3, 4, 6, 14-18, absent evidence to the contrary.

18. Claims 1,3-6, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayashi et al (US Patent 5,739,008)

Hayashi et al disclose polynucleotide encoding actin, vector comprising said polynucleotide, cell comprising said cell and method of using the cell to produce the encoded polypeptide. Actin inherently binds afadin (see supporting document US Patent 6,180,760). Therefore the disclosure of the Hayashi et al meets the limitations of claims 1,3-6, 15 absent evidence to the contrary.

19 No claim is allowed.

Advisory

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nirmal S. Basi
Art Unit 1646
8/17/06

GARY B. NICKOL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600